

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MARKS & CLERK
Tower Building
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Liverpool L3 1BA
GRANDE BRETAGNE

21 NOV 2005

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

| | | | |
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| | | Date of mailing (day/month/year) | 17.11.2005 |
| Applicant's or agent's file reference KJL/CT/P5367 | | IMPORTANT NOTIFICATION | |
| International application No. PCT/GB2004/005166 | International filing date (day/month/year) 09.12.2004 | Priority date (day/month/year) 09.12.2003 | |
| Applicant ZI MEDICAL PLC et al. | | | |

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

| | | |
|--|--|---|
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Eich, M Tel. +49 89 2399-7578 |  |
|--|--|---|

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | | |
|---|---|--|-----------------------|
| Applicant's or agent's file reference KJL/CT/P5367 | FOR FURTHER ACTION | | See Form PCT/APEA/416 |
| International application No. PCT/GB2004/005166 | International filing date (day/month/year) 09.12.2004 | Priority date (day/month/year) 09.12.2003 | |
| International Patent Classification (IPC) or national classification and IPC A61M5/145, F16H19/02 | | | |
| Applicant ZI MEDICAL PLC et al. | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of 6 sheets, as follows:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | |
| <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input checked="" type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application | | | |
| Date of submission of the demand 26.09.2005 | Date of completion of this report 17.11.2005 | | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Reinbold, S Telephone No. +49 89 2399-7918 | | |



404582426

International application No.
PCT/GB2004/005166INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY

iAP20 Rec'd PCT/PTO 08 JUN 2006

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-12 as originally filed

Claims, Numbers

1-21 filed with telefax on 26.09.2005

Drawings, Sheets

1/6-6/6 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/005166

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|------|--------|------|
| Novelty (N) | Yes: | Claims | 1-21 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-21 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-21 |
| | No: | Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

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Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement.

1. Reference is made to the following documents:

D1: FR 1562416
 D2: FR 2541395
 D3: US 4253342
 D4: JP 10297478
 D5: US 5006112

Novelty Article 33(2) PCT and Inventive Step Article 33(3) PCT

2. The present application does appear to meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-21 seems to be new and inventive in the sense of Article 33(2) and (3) PCT.

The document D5 is regarded as being the closest prior art to the subject-matter of claim 1 and discloses (the references in parentheses applying to this document) a syringe driver assembly for imparting translation movement to a syringe plunger (4).

The subject-matter of claim 1 therefore differs from this known syringe driver assembly in that:

- the driver means comprising a motor driven unthreaded shaft
- at least one bearing mounted obliquely to the shaft and having at least one point of contact therewith
- an actuator linked to at least one bearing for contacting a thumbplate of the plunger wherein rotation of the shaft causes movement of the at least one bearing along the shaft to affect movement of the actuator.

The problem to be solved by the present invention may therefore be regarded as how to avoid reduction in performance of the syringe driver assembly that can occur when dirt ingresses into the threads of a threaded bar.

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/GB2004/005166

No document of the search report discloses a syringe driver assembly with a unthreaded shaft and at least one bearing mounted obliquely to the shaft.

The documents D1 to D4 disclose driver assemblies with a unthreaded shaft and bearings mounted obliquely but no syringe driver assembly. It is not evident to combine the devices described in D1 to D4 with D5 because they relate to industrial appliances of a larger size.

Therefore the subject matter of claims 1-21 is considered to meet the requirement of Article 33 (1) PCT in respect of novelty and inventive step.

Re Item VII

Certain defects in the international application

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein. D1 does not disclose a syringe driver but a driver means with a unthreaded shaft and at least one bearing mounted obliquely.

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Title: An improved feed mechanism for a medical device.

DESCRIPTION

The present invention relates to an improved feed mechanism for a medical device, particularly but not exclusively a syringe driver or pump.

Syringe drivers or pumps are well known. They are small, lightweight, battery operated machines that are designed to administer subcutaneous infusions of a prescribed amount of medication over a given period. A syringe driver basically consists of the machine itself, a syringe containing the medicine to be administered which is attached to the machine and a thin piece of tubing attached to the syringe which has a needle at the end of it. Syringe drivers are often provided with both the machine and the syringe contained within a housing to increase the portability of the device.

The drive mechanism for driving the plunger through the syringe barrel to dispense medication generally consists of a motor, gears and a threaded shaft. The motor causes rotation of the threaded shaft which, via an actuator attached thereto, effects movement of the plunger (for example, see US 5,006,112). Once the required medication has been dispensed, it is necessary to manually reset the syringe driver by pulling back the actuator and syringe plunger to the required degree. Conventionally, this is achieved by the provision of two half nuts around the threaded shaft, the



manual disengagement of which enables the actuator to be moved back to the end of the shaft to allow the plunger to be reset. However, these nuts are subject to a large amount of wear and tear and thus require frequent replacement. Furthermore, once the nuts have become worn, the shaft will still rotate placing a load on the motor but without imparting any movement to the actuator.

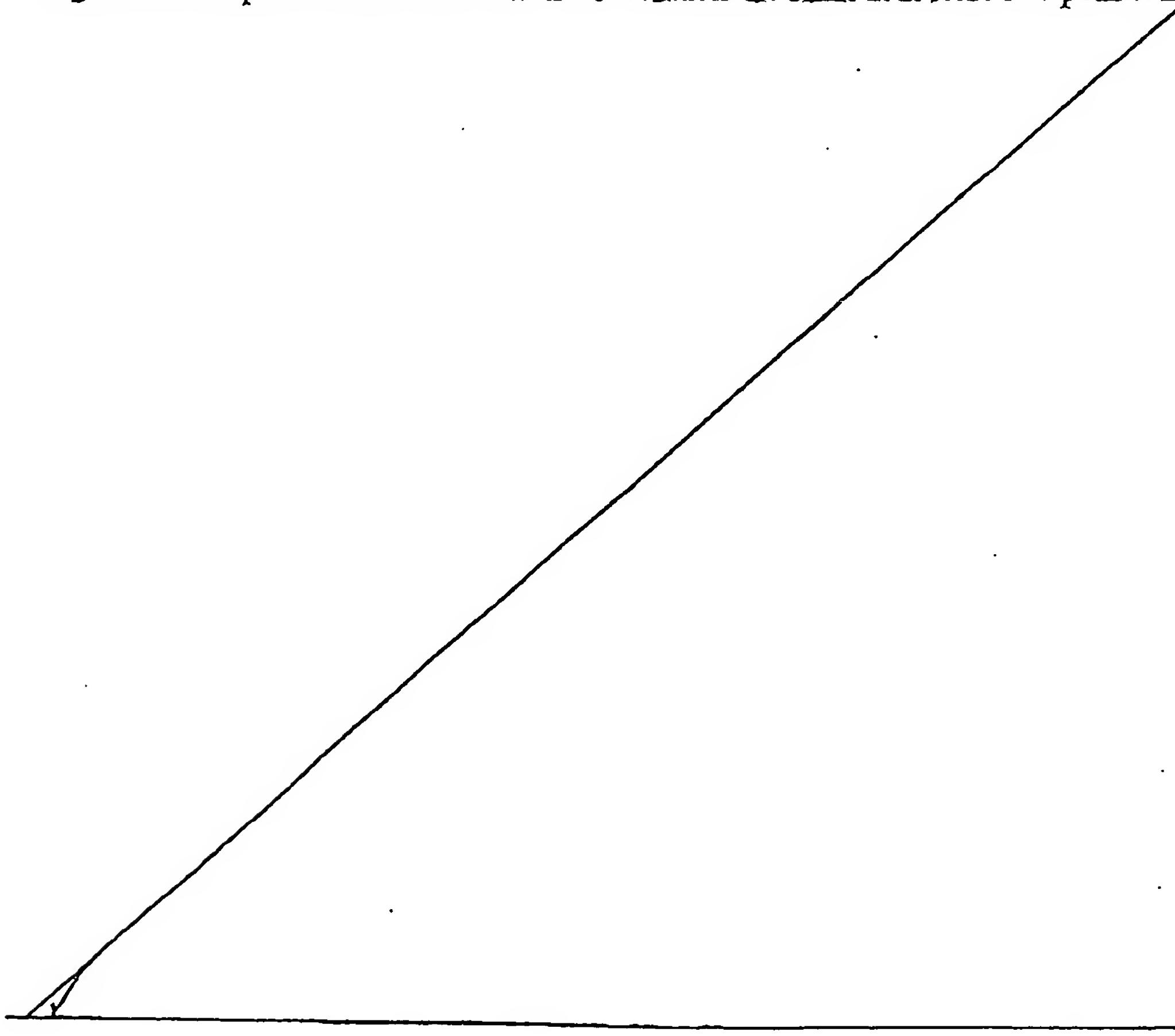
It is an object of the present invention to provide an improved feed mechanism for a medical device, particularly but not exclusively a syringe driver or pump that aims to overcome, or at least alleviate the abovementioned drawbacks.

Accordingly, a first aspect of the present invention provides a syringe driver assembly comprising driver means for imparting translational movement to a syringe plunger, the driver means comprising a motor driven unthreaded shaft, at least one bearing mounted obliquely to the shaft and having at least one point of contact therewith, and an actuator linked to the at least one bearing for contacting a thumb plate of the plunger wherein rotation of the shaft causes movement of the at least one bearing along the shaft to affect movement of the actuator.

If only a single bearing is provided, the shaft should be supported at one or more points along its length by a rotary member. The rotary member should be provided on the opposite side of the shaft to the contact point of the bearing.

However, in a preferred embodiment, more than one bearing is mounted obliquely to the shaft, especially three bearings, each having a bore through which the shaft extends. More preferably, alternate bearings are set at the same angle relative to the shaft and adjacent bearings are set at an opposing angle relative to the shaft. The bore of each bearing should be larger than the outer circumference of the shaft to result in each bearing being oversized with respect to the shaft, thereby creating clearance between the shaft and each bearing.

The inner profile of the bearings may be flat or pointed. Preferably, bearings having a flat inner profile with a chamfered inner race are used, each bearing being angled with respect to the shaft such that it contacts the shaft at at least two points. In



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CLAIMS

1. A syringe driver assembly comprising driver means for imparting translational movement to a syringe plunger, characterised in that, the driver means comprising a motor driven unthreaded shaft (200), at least one bearing (260, 270, 280) mounted obliquely to the shaft and having at least one point of contact therewith, and an actuator (800) linked to the at least one bearing for contacting a thumbplate of the plunger wherein rotation of the shaft causes movement of the at least one bearing along the shaft to affect movement of the actuator.
2. A syringe driver assembly as claimed in claim 1 wherein a single bearing is provided and the shaft is supported at one or more points along its length by a rotary member.
3. A syringe driver assembly as claimed in claim 2 wherein the rotary member is provided on an opposite side of the shaft to the contact point of the bearing.
4. A syringe driver assembly as claimed in claim 1 wherein at least three bearings (260, 270, 280) are provided with alternate bearings (260, 280) being mounted at the same angle relative to the shaft (200) and adjacent bearings (260, 270) being mounted at an opposing angle relative to the shaft.
5. A syringe driver assembly as claimed in any one of claims 1 to 4 wherein each bearing has a bore through which the shaft passes, the bore being larger than the outer circumference of the shaft.
6. A syringe driver assembly as claimed in claim 5 wherein the bearing has a pointed inner profile.

7. A syringe driver assembly as claimed in claim 5 wherein the bearing has a flat inner profile with a chamfered inner race.
8. A syringe driver assembly as claimed in claim 7 wherein each bearing is angled with respect to the shaft such that it contacts the shaft at at least two points.
9. A syringe driver assembly as claimed in any one of claims 4 to 8 wherein three bearings are provided, the outer bearings contacting the bottom of the shaft and the central bearing contacting the top of the shaft or vice versa.
10. A syringe driver assembly as claimed in any one of the preceding claims wherein the angle of inclination of each bearing (260, 270, 280) relative to the shaft (200) is less than 45 degrees.
11. A syringe driver assembly as claimed in any one of claims 1 to 4 wherein the inclined bearings are symmetrically spaced in one plane perpendicular to the shaft axis, the outer races of the bearings making radial contact with the shaft.
12. A syringe driver assembly as claimed in claim 12 wherein the bearing is spring loaded.
13. A syringe driver assembly as claimed in any one of the preceding claims wherein the or each bearing (260, 270, 280) is housed within a carriage (400) that is moveable with respect to the shaft (200).
14. A syringe driver assembly as claimed in claim 12 wherein the carriage (400) is connected to the actuator (800).
15. A syringe driver assembly as claimed in claim 14 wherein the carriage is provided with guides.

16. A syringe driver assembly as claimed in any one of the preceding claims wherein the means is provided for manually disengaging the at least one bearing (270) to enable it to slide independently of the shaft (200).
17. A syringe driver assembly as claimed in claim 16 wherein a bearing is spring-loaded with respect to the shaft whereby operation of the spring mechanism disengages the bearing from the shaft.
18. A syringe driver assembly as claimed in claim 16 wherein manual disengagement is affected by movement of a housing (370) containing a bearing (270) in a direction transverse to the shaft to lift the bearing from the shaft.
19. A syringe driver assembly as claimed in claim 18 wherein a cam (500) and lever is used.
20. A syringe driver assembly as claimed in any one of claims 1 to 15 wherein automatic means is provided for reversing the direction of travel of the bearings and actuator along the shaft.
21. A syringe driver assembly as claimed in any one of the preceding claims wherein the bearing is provided with adjustable biasing means (502, 504, 506).